

Recent Significant Updates to the Stark Law and Anti-Kickback Statute

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The Stark Law and Anti-Kickback Statute (AKS) place significant restrictions on how providers and businesses can operate in the health care space. The existing restrictions are helpful in fighting fraud but also potentially inhibit beneficial arrangements that could advance transition from a fee for service model to one with an increased focus on value-based care and coordination of patient care. The hope is that paying for value will result in improved outcomes, lower costs or reduced growth in costs. The recent AKS and the Stark Law updates are designed to offer the health care industry more flexibility and to reduce the regulatory burden in certain areas, particularly value-based arrangements and care coordination.

There are new value-based exceptions under the Stark Law and safe harbors under AKS. Helpfully, the same terminology and definitions were used for both, and the final regulations mirror each other as much as possible.

The new value-based Stark Law exceptions do not require that compensation be set in advance, consistent with fair market value, or determined in a manner that does not take into account the volume or value of the physician's referrals or other business generated by the physician; however, they must still be commercially reasonable. The requirements depend, in part, whether there is full financial risk, meaningful downside risk or neither.

The new value-based AKS safe harbors are for care coordination arrangements to improve quality, health outcomes, and efficiency; value-based arrangements with substantial downside financial risk; and value-based arrangements with full financial risk. There are important details for each. For example, although the coordination arrangements safe harbor does not require the participants to take on risk, it only permits in-kind remuneration and must be measured based on at least one evidence-based outcome measure (among other restrictions).

The updates to the Stark Law and AKS are not limited to value-based arrangements. For example, the definition of "set in advance" under AKS has been updated, and donations of certain cybersecurity software and services are now permitted under the electronic health record exception.

Do not hesitate to contact any member of Bodman's Health Care Group to discuss these implications or other health care matters affecting your organization. Members include the chair of our Healthcare Law Group, Joe Nuyen, at (313) 392-1071 or jnuyen@bodmanlaw.com or the assistant chair, Brandon Dalziel, at (313) 393-7507 or bdalziel@bodmanlaw.com. Bodman cannot respond to your questions or receive information from you without first clearing potential conflicts with other clients. Thank you for your patience and understanding.